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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,129	03/08/2004	Gera Strommer	02649/0200987-US0	6958

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SJM/AFD - DYKEMA
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EXAMINER	
CHAO, ELMER M	
ART UNIT	PAPER NUMBER
3737	
MAIL DATE	DELIVERY MODE
09/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,129	STROMMER ET AL.	
	Examiner	Art Unit	
	ELMER CHAO	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,26,27,29-33,35 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,26,27,29-33,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/2/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of the amendment filed 9/2/2009.

2. Acknowledgement is made of the Information Disclosure Statement filed 9/2/2009.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/13/2009 has been entered.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claims 27, 29, 30, 32, 33, and 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilboa (U.S. 2002/0193686) in view of Werp et al. (U.S. 6,015,414), and further in view of Ferry et al. (U.S. 7,276,044 B2).

Regarding **claim 33**, Gilboa teaches a method of navigating a probe including the steps of:

establishing a path in said lumen system from a topological representation of the lumen system (Para [0016], establishing a path would be necessary in order to move the catheter); determining a first position of said catheter in said path (Para [0028], " ..."probe" as used herein should be construed as including...a catheter"; Para [0016], "estimating a location of the target point-of –interest") according to a position signal received of the first position of a distal portion of said catheter (Para [0016], "measuring a location of the probe relative to the reference frame"), and also determining a new position to which said catheter is to be moved based on said determined first position (Para [0016], "moving the probe, within the body cavity, so as to minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest") and according to said path from said topological representation (Para [0016], "acquiring a plurality of projective images of at least a portion of the body cavity");

operating a moving mechanism (see below) to move said catheter to a second position, according to said new determined position (Para [0016], "moving the probe, within the body cavity");

receiving a position signal as said catheter is moved during said operating step (Para [0016], "measuring a location of the probe relative to the reference frame"), when said second position is substantially identical with said new determined position, determining a further new positions on said path to which said catheter is to be moved and, when said second position is not identical with said new determined position, determining at least one corrective movement for said catheter (Para [0016], "moving the probe, within the body cavity, so as to minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest", see below);

and directing said moving mechanism to move said catheter according to said determined corrective movement (Para [0016], "moving the probe, within the body cavity, so as to minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest").

Para [0016] does not explicitly state using a "moving mechanism" to move the catheter. However, it is inherent to use some type of "moving mechanism" in order to move the catheter into and within the body, otherwise it would be impossible to move the catheter. It is well known in the art that this moving mechanism is traditionally simply the operator's hands, or, at other times, a mechanical moving mechanism can be used.

Para [0016] also supports the use of "corrective movements." In order to "minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest" (Para [0016]), it is necessary for the operator to move the catheter towards the point-of-interest with one or more corrective movements.

Gilboa teaches performing the medical procedure after the navigation of the catheter (Para [0066], "The present invention is of a method of performing invasive medical procedures ... such as stent deployment in a coronary artery").

Gilboa teaches the limitations as discussed above but fail to explicitly teach at least one corrective movement when the orientation does not match the slope of the path at a certain location. However, in the same field of endeavor, Werp et al. teach at least one corrective movement when the orientation does not match the slope of the path at a certain location (Fig. 4). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Gilboa to include the correction procedure in order to more accurately navigate the catheter to a destination (col. 4, lines 22-62).

Gilboa and Werp et al. teach the limitations as discussed above but fail to explicitly teach the at least one corrective movement involving a backwards movement. However, in the same field of endeavor, Ferry et al. teach a method of withdrawing a catheter (col. 9, lines 16-35). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include a backwards movement during the guidance procedure in order to reduce static friction (for explicit motivation see col. 9, lines 16-20). Additionally, pulling the catheter when an ideal position is not

reached is considered an obvious navigation technique (pg 1, line 20 - pg 2, line 7, Specification), and the present invention can be considered automating this originally manual activity (see *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)).

Regarding **claim 32**, Gilboa teaches moving a catheter in the longitudinal direction. Such a movement is a necessary action when pushing/moving/guiding a catheter to a location of interest.

Regarding **claim 27**, Gilboa further teaches the topological representation being produced by indicating an origin and a destination on an image of at least a portion of said lumen, in a coordinate system respective of said body.

(Para [0074], "...the user changes the coordinates of the point represented by the icon until the icon coincides with the projection of the point-of-interest on each of the images."; Para [0076], "...only icons representing the locations of the points-of-interest are displayed on a display unit ...along with an icon representative of the true location of the catheter relative to the points of interest"); Para [0077], "if so desired, the points of interest may be displayed superposed on one of the images, from the point of view at which that image was acquired").

Regarding **claims 29 and 30**, Gilboa further teaches the invention wherein said image is produced by imaging said at least one portion, at least one unparallel imaging planes, one of which is closest to said predetermined path among a plurality of other image planes (Para [0080]).

Para [0080] discloses, "...several images of coronary artery tree 28 are acquired...from several angles; also see figure 3 for "unparallel imaging planes".

Regarding claim 29, among the several images, a "closest image" is inherently and necessarily acquired, "closest" being relative to the distances of the other images. Regarding claim 30, Gilboa's technique of acquiring images of the coronary artery tree from several angles implies the images all contain at least a portion of the lumen system of interest, thereby inherently disclosing an "overlap" within the images.

Regarding **claims 36,** Gilboa, Werp et al., and Ferry et al. teach the limitations as discussed above but fail to explicitly teach a corrective movement that includes twisting the distal portion of the catheter. However, the instant application admits that manually twisting the catheter is known in the art (pg 1, line 20 - pg 2, line 7, Specification). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include twisting the catheter as part of a corrective movement as it can essentially be considered using a moving mechanism to automate a manual activity (see *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)).

7. **Claims 18, 26, 31, and 35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilboa in view of Werp et al., further in view of Ferry et al., and further in view of Strommer et al. (U.S. 2001/0031919 A1).

Regarding **claim 18,** Gilboa, Werp et al., and Ferry et al. teach the limitations as discussed above. They do not explicitly teach updating at least one of said topological representation according to an organ timing signal of an organ timing monitor coupled with a monitored organ of said body. However, Strommer et al. teach the real-time reading of an organ timing signal for real-time visualization of the inspected organ which

is then used to update the 3D image of the body (Para [0046]; also see claim 26). Strommer et al. also goes on to teach controlling the said moving mechanism according to the updated topological representation (Para [0047]). Therefore, it would have been obvious to a person of ordinary skill in the art to include the use of an organ timing monitor in the application of updating topological images as evidenced by Strommer et al. Such a modification would allow for a moving organ to be displayed in real-time (Para [0021]).

Regarding **claim 26**, Strommer et al. teach said display being used to display a superimposed topological representation on the display (paragraph 0047), which would require a 3D to 2D transformation in order for the 3D location to be matched to a 2D topological representation.

Regarding **claim 31**, Gilboa, Werp et al., Ferry et al. teach the limitations as discussed above but do not explicitly teach the step of determining the shape of said distal portion. However, Strommer et al. teach the possibility of extrapolating the shape of the surgical tool through a reconstructed 3D image (Para [0076]). It would have been obvious to a person of ordinary skill in the art to include the step of determining the shape of the distal portion of the catheter as evidenced by Strommer et al. Such a modification would create a more detailed image of the catheter so that the operator can more precisely navigate it.

Regarding **claims 35,** Gilboa, Werp et al., Ferry et al., and Strommer et al. teach the limitations as discussed above but fail to explicitly teach a corrective movement that includes twisting the distal portion of the catheter. However, the instant application

admits that manually twisting the catheter is known in the art (pg 1, line 20 - pg 2, line 7, Specification). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include twisting the catheter as part of a corrective movement as it can essentially be considered using a moving mechanism to automate a manual activity (see *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)).

Response to Arguments

8. Applicant's arguments filed 8/13/2009 have been fully considered but they are not persuasive.

9. Applicants argue that Gilboa does not teach some of the procedures of claim 33 (page 6, fourth paragraph, Arguments). Examiner notes that the cited para [0016] was meant to teach the feature "determining a new position to which said catheter is to be moved based on said determined first position" as recited in claim 33. The fact that para [0016] explicitly discloses "moving the probe, within the body cavity, so as to minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest", shows that Gilboa is teaching detecting the current position of the tip of the catheter and determining the new position of where the catheter must go, since the "estimated location" would require a prior determining step.

10. Applicants argue extensively that Ferry does not teach a backwards *corrective* movement (emphasis added) (page 7, third paragraph, Arguments). Applicants also argue that Werp does not teach a corrective movement (page 8, last paragraph, Arguments). In both cases, Applicants argue that neither references have what the

Applicants deem a proper correction movement. However, Examiner notes that a "corrective movement" can be any movement that helps in the ultimate goal, which is to achieve the intended destination for the catheter. Just because Applicants have a different idea of how their backwards movement is employed in the whole scheme of the navigation does not preclude the use of a stuttering type movement as taught by Ferry or a vector correction movement as taught by Werp. The claims do not recite limitations precluding the use of Werp's vector correction or Ferry's stuttering correction.

11. Applicants further argue that even if a person of ordinary skill in the art were to employ the techniques of all three references, the corrective movement of the present invention would still not be achieved (page 9, first and second paragraphs, Arguments). Examiner notes that this is not true. One of ordinary skill in the art at the time of the invention would understand that the combination would yield an invention where, if the second position is not identical with said new determined position then the "stuttering correction" of Ferry would be employed. Of course, Applicants would be keen to also realize that if the second position *is* identical with the said new determined position then the "stuttering correction" would still be employed (emphasis added). Either way, the claim's condition of the backwards correction movement would still be met when the condition is true.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELMER CHAO whose telephone number is (571)272-0674. The examiner can normally be reached on Mon-Thurs 11am-9pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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